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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/694,077	RAVKIN ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34 and 36-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34 and 36-47* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/8/08; 3/3/08*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed January 8, 2008 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 34 and 36-47 were pending. Applicants amended claims 34, 37, 40, 41, 44 and 47. No claims were added or canceled. Therefore, claims 34 and 36-47 are still pending and examined on the merits.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C.120 and/or 119(e) as follows:

The present application is a CIP of 09/549,970 (filed 4/14/2000), which claims benefit of 60/129,664 (filed 4/15/1999) and also claims benefit of 60/170,947 (filed 12/15/1999). The present application also claims benefit to 60/2441,714 (filed 10/18/200).

The later-filed application must be an application for a patent for an invention which is

also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

However, one or more of the applications stated above fail to provide adequate support under 35 U.S.C. § 112, first paragraph for the claimed invention as follows:

> (A) For ***claims 34, 41, and all dependent claims***, provisional applications 60/129,664 and 60/170,947 fail to provide support for "providing a first class of carriers in a first vessel, each carrier in the first class having a first optically detectable code, and a second class of carriers in a second vessel, each carrier in the second class having a second optically detectable code." In addition, these provisional applications also fail to provide support for a first/second class of carriers that comprise distinct shapes in addition to the distinct codes.
>
> (B) For ***claims 36, 43, and all dependent claims***, provisional applications 60/129,664 and 60/170,947 fail to provide support for the "transparent" section.
>
> (C) For ***claims 37, 44 and all dependent claims***, provisional applications 60/129,664 and 60/170,947 fail to provide support for the "combination of fused fibers of various colors."
>
> (D) For ***claims 39, 46 and all dependent claims***, provisional applications 60/129,664 and 60/170,947 fail to provide support for the "covalent" attachment.
>
> (D) For ***claims 34, 42 and all dependent claims***, provisional applications 60/129,664 and 60/170,947 fail to provide support for the "substantially perpendicular" limitation.

If applicant believes this assessment is in error, applicant must disclose where in the specification support for these limitations can be found. Therefore, the earliest effective priority date is deemed to be **April 14, 2000** for application 09/549,970.

Withdrawn Objections/Rejections

5. The 35 U.S.C. § 112, second paragraph rejections denoted A-D are withdrawn in view of Applicants' amendments to claims 34, 37, 40, 41, 44, and 47. The 35 U.S.C. § 130(a) rejection is withdrawn in view of Applicants' amendments to the claims.

New Rejections/Objections

Objection to the Claims

6. Claim 34 is objected to because of the following informalities:

A. Newly amended claim 34 reads, "the carriers has" in line 7. Correction is requested.

35 U.S.C. § 103(a)

7. Claims 34 and 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al. (Lam, K. S.; Salmon, S. E.; Hersh, E. M.; Hruby, V. J.; Kazmierski, W. M.; Knapp, R. J. "A new type of synthetic peptide library for identifying ligand-binding activity" Nature **1991**, 354, 82-84) (of record) and Egner et al. (Egner, B. J.; Rana, S.; Smith, H.; Bouloc, N.; Freg, J. G.; Brocklesby, W. S.; Bradley, M. "Tagging in combinatorial chemistry: the use of colored and fluorescent beads" Chem. Commun., **1997**, 735-736) (of record) and Lee (U.S. Patent No. 4,053,433) (Date of Patent is **1977**) (of record) and Natan et al. (U.S. Patent No. 7,225,082) (1/8/07 IDS, A32) (earliest priority to **October 1, 1999**) and Blawas et al (Blawas, A.S.; Reicher, W. M. "Protein Patterning" Biomaterials **1998** *19*, 595-609) (of record) and Noonan et al. (U.S.

Patent No. 6,129,896) (Filing Date is **December 17, 1998**) (of record) and Dunlay et al. (WO 98/38490) (Date of patent is **September 3, 1998**) (1/8/08 IDS, B3).

For ***claims 34 and 41***, Lam et al. (see entire document) teach a method for conducting a multiplexed experiment (e.g., see abstract wherein the 'one-bead, one peptide' approach is disclosed), which renders obvious the claimed invention. For example, Lam et al. disclose providing a first class of carriers in a first vessel and a second class of carriers in a second vessel wherein a first type of analyte is coupled to the first class of carriers in the first vessel and a second type of analyte is coupled to a second class of carriers in the second vessel and forming a mixture of carriers from the first vessel and the second vessel, the mixture having substantially equal number of carriers from each vessel (e.g., see page 82, column 1, last paragraph, "The first cycle consisted of distributing a pool of resin beads into <u>separate reaction vessels</u> each with a single amino acid [i.e., different class of analyte]"; see also figure 1, wherein the first class = A, second class = G, etc. and each class is in its own reaction vessel; see also page 82, column 2, paragraph 3 describing the formation of pentapeptide library with ~2,476,099 members; see also figure 1, "randomization" step; see also page 82, column 1, last paragraph, "Our method involves creating a large peptide library … representing the universe of possible random peptides in <u>roughly equimolar proportion</u>"). Lam et al. further disclose randomly dispersing a portion of the mixture to an examination site on a surface (e.g., see figure 2; see also page 82, column 2, paragraph 1). Lam et al. also disclose contacting the portion of the mixture with a test substance such as a labeled

antibody against β-endorphin or streptavidin (e.g., see Lam et al., Tables 1 and 2; see also figure 2). Lam et al. also disclose acquiring at least one image of at least a portion of the mixture of carriers at the examination site on the surface (e.g., see figure 2 showing low- and high-power photomicrographs). Lam et al. also disclose directing an imaging device toward the examination site, the imaging device being configured to acquire images of carriers at the examination site and acquiring a set of images of carriers at the examination site (e.g., see Lam et al., figure 2 wherein images are displayed).

For ***claims 39 and 46***, Lam et al. disclose covalent attachment of pentapeptide sequences (e.g., see figure 1; see also abstract).

For ***claims 40 and 47***, Lam et al. disclose a reaction step that occurs before the dispensing step (e.g., see Lam et al., page 82, column 2, paragraph 1, "Acceptor molecules were … added in soluble form to the peptide-bead library [i.e., before analysis]"). Also note that optimization of process steps, especially with respect to ordering, is within the routine skill of the art. *In re Burhans*, 154 F.2d 690, 69 USPQ330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results).

<u>Lam et al. differ from the claimed invention as follows</u>:

For ***claims 34 and 42***, Lam et al. fail to teach the use of a first and second optically detectable code to interpret the result of such a binding experiment. Lam et al. only teach the use of labels such as alkaline phosphatase coupled with various sequencing techniques to identify pentapeptides that interact with the ligands. In addition, Lam et al.

fail to teach carriers with at least one flat viewing surface and a shape that self-orients the viewing surface to face a viewing direction. Lam et al. only teach the use of round beads. Lam et al. also fail to teach carriers that comprise a distinct shape from each other. Lam et al. only teach the use of beads.

For ***claims 36 and 43***, Lam et al. fail to teach each carrier has at least one transparent portion.

For ***claims 37 and 44***, Lam et al. fail to teach carriers as a combination of fused fibers of various colors, the colors and relative positions of the fibers indicating the code.

For ***claim 38 and 45***, Lam et al. fail to teach the attachment of biological cells to the carriers for cell identification. Lam et al. only teach the use of peptides.

For ***claim 41***, Lam et al. fail to teach wherein each image corresponds to a different spectral band and operating a computer program to identify carriers of the same class by using the images to develop a mask of carriers of the same class and detecting one or more reporting modalities with the mask.

<u>However, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach the following limitations that are deficient in Lam et al.</u>:

For ***claims 34 and 42***, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach the use of a first and second class of detectable codes to aid in the identification (i.e., interpretation) of a library of peptides

(e.g., see Egner et al., figures 1 and 4; see also footnotes disclosing that various dyes can be used to label each "class" of library member such as pyrene butanoic acid for Valine, methyl red for alanine, etc.; see also Natan et al., abstract and figures disclosing the use of microbars to label various classes of substituents including peptides/proteins). In addition, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach that the carriers have at least one flat viewing surface and a shape that self-orients the viewing surface to face a viewing direction (e.g., see Lee, figures 2-5 disclosing examples of a planar "top" and a planar "bottom" side that are substantially parallel and flat; see also lines 37-38 showing that these taggants are useful for producing "libraries" like the libraries disclosed by Lam et al.; see also Natan et al., column 8, line 9; see especially paragraph bridging columns 6 and 7, "the cross-sectional shape of the particles, viewed along the long axis, can have any shape … [including] square"; see also figures 5 and 6 showing an orientation that faces the viewing surface). The combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. also teach carriers that have different shapes in addition to the different optically detectable codes (e.g., see Natan et al., column 3, lines 44,-48, "In the preferred embodiments, the particle types are <u>differentiable based on differences</u> in the length, width or <u>shape</u> of the particles <u>and</u>/or the number, compositions, length of pattern of said <u>segments</u>").

For ***claims 36 and 43***, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach a transparent portion (e.g., see Lee,

column 3, lines 60-62, “A list of suitable colors may include: Clear”).

For ***claims 37 and 44***, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach fused colored fibers wherein said fibers represent the code (e.g., see Lee, figures 2-5, see also column abstract, see also column 2, Summary of Invention, wherein the code is detectable on either planar side; see also column 4, lines 49-52, “A preferred type of color-coded microcarrier ... consists of microscopic pieces of colored plastic films fused together to form a rectangular ‘microsandwich’”; see also column 4, lines 46-48; see also, column 2, line 46 disclosing 233,846,052 uniquely coded batches of microcarriers; see also see figure 5 disclosing fused fibers; see also Natan, figure 5 showing fused fibers).

For ***claims 38 and 45***, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach the attachment of biological cells to the carriers for cell identification (e.g., see Noonan et al, column 2, lines 23-26; see also column 2, last three paragraphs, “Method 100 begins by synthesizing functional moieties onto a plurality of fibers ... For example, functional moieties may include DNA oligonucleotides for DNA testing biosensor devices. Alternative, the functional moieties may include proteins, peptide, Antibodies”; see also Blawas et al, pages 605-606, section 4.3, wherein Blawas et al disclose that bound proteins and/or antibodies can be used to control the areas of cell adhesion and/or growth to a substrate surface i.e., the cells bind to the proteins that are attached to the fused glass and/or plastic chips; see also Natan et al., column 14, lines 25-30, “Although many embodiments are focused on antibody-based

detection schemes, it should be recognized that these principles apply equally well to detection of … cells”).

For ***claim 41***, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach wherein each image corresponds to a different spectral band and operating a computer program to identify carriers of the same class by using the images to develop a mask of carriers of the same class and detecting one or more reporting modalities with the mask (e.g., see Egner et al., figure 1 showing identification of beads using different spectral bands; see also Dunlay et al., page 31, last paragraph describing the use of a segmentation procedure for selecting desired objects over unwanted artifacts using a binary image call a “mask”; see also paragraph bridging pages 37 and 38 again describing the use of a masking technique to find initial “hits” that can subsequently be analyzed for “high content” processing; see also figures 12 and 13; see also paragraph at bottom of page 38; see also top of page 39 wherein the system performs “multiple tests” by applying “several analytical methods to measure features at each of several wavelengths” when the object has been determined to be something other than an unwanted artifact).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make/use the colored and/or fluorescently labeled beads as disclosed by Egner et al. for the purpose of encoding a peptide library as disclosed by Lam et al. because Egner et al. expressly state that their labeled beads were created for this purpose (e.g., see Egner et al., page 736, paragraph bridging columns 1-2, “The use

has the potential, we believe, to simplify the identification of library members for single bead screening application"; see also page 735, column 1, paragraph 3, wherein the Lam et al. article is explicitly cited in footnote number 2). Furthermore, one of ordinary skill in the art would have been motivated to use the colored and labeled beads as taught by Egner et al. because according to Egner et al. it is a "simple" technique that is "non-destructive" and "very sensitive, with detection levels easily down to femtomoles of material/bead" (e.g., see Egner, et al., page 736, column 1, last paragraph). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Egner et al. actually use the method of Lam et al. to synthesize their library (e.g., see Egner et al, page 735, column 1, paragraph 3 wherein the Lam et al. reference is cited for the library preparation in footnote 2).

In addition to the spherical beads disclosed by Lam et al. and Egner et al., other art recognized carriers (with different shapes and chemical compositions) would have likewise been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007) (noting that mere substitution of one component for another to yield predictable results represents a prima facie case of obviousness). For example, the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. teach the use of various other carriers that were standard in the art at the time the invention was made for making/screening libraries (e.g., see Lee, abstract expressly stating that their taggants can be used to label chemicals; see also figures 2-6;

see also column 2, lines 37 and 38 wherein Lee expressly state that these taggants are useful for the production of "libraries"; see also column 1, lines 57 wherein the screening of "proteinaceous" materials are disclosed like the "proteinaceous" peptide libraries disclosed by Lam et al; see also Noonan et al., figure 3; see also column 2, lines 60-63 stating that similar fused fibers can be used to "attach" a wide variety of ligands including proteins, antibodies, nucleic acids, etc.; see also Natan et al., abstract and figures disclosing the use of microbar encoders). Furthermore, these substitute carriers provide many advantages over the beads disclosed by Lam et al./Egner et al. including (1) ease of manufacture, (2) increased "quality control" through the use of "cleavable linkers, (3) cost advantages, (4) chemical/physical stabilization, (4) increased solvent exposure for the biomolecules immobilized thereto and (5) access to a larger number of codes that enables the screening of a larger number of library members (e.g., see Noonan et al., column 2, paragraph 1; see also Natan et al. column 6, paragraph 1 discussing increased solvent exposure; see also Lee, column 2, lines 22-23, see also lines 28-45, "The improvement ... comprises providing microcarriers ... [that] are encoded according to, a particular orderly sequence of visually color distinguishable dyed and/or pigmented layers ... For example, using a library of 12 colors in an eight-membered sequence, wherein no color is used adjacent to itself, the number of codes would be determined as follows ... this system includes 233,846,052 possible codes"). Finally, a person of skill in the art would reasonably have been expected to be successful because the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al.

disclose that proteins, peptides, nucleic acids, and antibodies can all be easily attached to these carriers just like the peptides were coupled to the beads in Lam et al. (e.g., see Noonan et al., column 2, second to last paragraph; see also figure 2 showing standard synthesis procedures for connecting peptides, proteins, nucleic acids etc. to the glass, plastic, polymer, etc. solid supports; see also Natan et al., column 15, paragraph 2). In addition, all of these carriers can be detected using an overhead optical/fluorescent scanning device like the one disclosed in Lam et al. (e.g., see Lam et al., figure 2; see also Egner et al., figure 1; see also Natan et al., figures 4 and 5, etc.).

Furthermore, it would also have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the carriers as taught by the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. for the purpose of tagging cells because the references expressly state that this can be done (e.g., see Noonan et al., abstract, column 2, Summary of the Invention; see also Blawas et al., page 605-606, section 4.3; see also Background of the invention and Table 1; see also Natan, column 15, line 30). A person of skill in the art would have been motivated to tag cells because immobilized biomolecules can be beneficially used to monitor cell adhesion and/or growth (e.g., see Blawas et al., entire document, especially, section 4.3 and figure 5; see also Natan, column 15, line 30). One of ordinary skill in the art would have reasonably expected to be successful because these references separately teach that many materials including fused glass, plastic, etc. may be used to label cells (e.g., see Blawas et al., Table I, Substrate column; see also Noonan et al., column 3, line

1; see also Lee, column 4, line 51).

Finally, it would also have been *prima facie* obvious to use a mask as described by the combined references of Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. (e.g., see Dunlay et al., see page 31, last paragraph; see also paragraph bridging pages 37 and 38; see also bottom of page 38; see also Example 1 describing the use of a mask to rapidly screen for objects of interest before) for the purposes of screening library members as taught by Lam et al. because Egner et al., Lee, Natan et al., Blawas et al., Noonan et al., and Dunlay et al. expressly state that a large number of targets can be distinguished from unwanted artifacts using this type of technique. In addition, a person of ordinary skill in the art would have been motivated to use this masking technique to enable high throughput screening of the library members by avoiding the unnecessary analysis of unwanted artifacts. Finally, a person of ordinary skill in the art would reasonably have expected to be successful because the masking technique as disclosed, for example, by Dunlay et al. can be used to detect optical/fluorescent chemical moieties like the ones disclosed by Lam et al./Egner et al. In addition, this technique can be used to detect biological cells like the ones disclosed by Blawas et al., Noonan et al., and Natan et al.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1/8/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/
Primary Examiner, AU 1639